Citation:

Rodríguez-Villar C, Pérez-Heras A, Mercadé I, Casals E, Ros E. Comparison of a high-carbohydrate and a high-monounsaturated fat, olive oil-rich diet on the susceptibility of LDL to oxidative modification in subjects with Type 2 diabetes mellitus. *Diabet Med.* 2004 Feb;21(2):142-9.

PubMed ID: 14984449

Study Design:

Randomized Crossover Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To compare the effects of a high-carbohydrate (CHO) diet and a high-monounsaturated fatty acid diet (MUFA) on LDL oxidative resistance among free-living subjects with type 2 diabetes.

Inclusion Criteria:

- Medically stable, adult patients with fairly well-controlled type 2 diabetes attending the out-patient lipid and diabetes clinics.
- BMI of less than 35
- Serum HbA1c of ≤ 8%
- Serum cholesterol ≤ 7.2 mmol/l
- Triglycerides ≤ 3.0 mmol/l
- Treatment with diet or oral hypoglycemic agents
- No intake of antioxidant vitamins or hypolipidemic drugs

Exclusion Criteria:

- Alcohol intake > 20 grams per day
- Diagnosis of diabetic enteropathy, renal disease, thyroid disease, or drug-treated hypertension

Description of Study Protocol:

Recruitment: patients attending an out-patient lipid and diabetes clinic at a university hospital lipid clinic in Barcelona, Spain.

Design Randomized, crossover trial in an out-patient setting.

Blinding used (if applicable): none mentioned

Intervention (if applicable)

- Two isocaloric diets (6 weeks duration), consisting of a higher carbohydrate diet and 28% fat energy vs. a MUFA diet with 40% of the kcals originating from fat (virgin olive oil).

Statistical Analysis

- Power analysis required 21 subjects
- Means and standard deviation for each measurement were calculated.
- Two-tailed t-tests were used to compare changes in the outcome variables.
- Difference testing between the two diets was performed using the analysis of covariance.
- Pearson's correlation coefficients and stepwise multiple regression analysis were used to evaluate predictors of LDL susceptibility to oxidation.

Data Collection Summary:

Timing of Measurements

- During a 6-week pre-inclusion period individuals consumed their usual diabetic diet low in SFA and high in CHO, followed by a 12-weel intervention with a crossover design
- No washout period was used
- Measurements were taken at baseline and during week 6 of each diet period.

Dependent Variables

- Change in LDL resistance to oxidation (average lag time of conjugated diene formation during Cu +2 induced oxidative stress in LDL)
- Changes in body weight (weight measurements, BMI calculations)
- Glycemic control (fasting blood glucose, hemoglobin A1c, and fasting insulin measurements)
- Serum lipoproteins (cholesterol, LDL, HDL, VLDL, TG, apolipoproteins)

Independent Variables

- Two isocaloric diets for 6 weeks each
- CHO diet was 28% fat
- MUFA diet was 40% fat, 40% CHO.
- The olive oil content of the MUFA diet was about 25% of energy requirements.

Control Variables

Description of Actual Data Sample:

Initial N: 26 adults (13 males, 13 females)

Attrition (final N): 22 adults, 12 men and 10 women.

Age: mean age of 61 ± 7 years, range of 52-75 years

Ethnicity: not reported

Other relevant demographics:

Anthropometrics average BMI about 27 to 28, average weight about 78-80 kg, and average waist circumference about 98-100 cm.

Location: Lipid Clinic at University Hospital, Barcelona, Spain

Summary of Results:

Key Findings

- Participants preferred the MUFA diet over the CHO diet.
- The lag time of conjugated diene formation during Cu+2 induced LDL oxidation was similar after the CHO and MUFA diets (36.4 ± 12.2 minutes and 36.0 ± 13.7 minutes, respectively).
- Body weight, glycemic control, total triglycerides, total cholesterol, LDL-cholesterol, and HDL-cholesterol levels were similar on both diets.
- Compared with the CHO diet, the MUFA diet lowered VLDL-cholesterol by 35% (P = 0.023) and VLDL triglyceride by 16% (P = 0.016).

Other Findings

- Compliance with olive oil intake was 100% based on the participant reports and empty container compliance.
- No side effects were reported for either diet.
- There were no differences between the two diets on apolipoproteins A and B or lipoprotein(a).

Author Conclusion:

In conclusion, the results of this study add to other clinical trials in type 2 diabetes, indicating that compared with a high-carbohydrate diet, a diet with a reasonable fat content based on MUFA-rich foods results in similar energy balance and glycemic control, and similar or improved lipid profiles. The data suggest that the resistance of LDL against oxidation is similar with the two dietary approaches. There are also other indications of anti-atherosclerotic effects of MUFA-rich foods in general and of olive oil in particular. The high-MUFA diet is palatable and a good alternative to a high-carbohydrate diets for medical nutrition therapy of type 2 diabetes.

Reviewer Comments:

No washout period used between diets. Relatively small sample size, but power analysis required 21 subjects and 22 completed.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A

3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	???
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	???
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes

6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	No
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes

9.2.	Are biases and study limitations identified and discussed?	???
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes